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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,782	KEKUDA R	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/16/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7-9,12-14,39,42 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5,7-9,12-14,39 and 42* is/are allowed.

6)☒ Claim(s) *50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on August 16, 2004 in response to the Restriction Requirement of June 16, 2004 is acknowledged and has been entered. Applicant has elected Group II, Claims 5-14, 39, and 42, drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide. Applicants further the nucleotide sequence SEQ ID NO: 15, encoding the polypeptide SEQ ID NO: 16. Further, Applicant has canceled claims 1-4, 6, 10-11, 15-38, 40-41, and 43-49 without prejudice or disclaimer as drawn to non-elected subject matter.

Applicant's election with traverse of Group II, claims 5-14, 39, and 42, drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide has been acknowledged. The traversal is on the ground(s) that the it would not present an undue burden for the Examiner to examine Group II, V and XV together, all with regards to a nucleic acid molecule SEQ ID NO: 15, encoding the polypeptide SEQ ID NO: 16. These arguments have been considered and are not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the restriction requirement of June 16, 2004.

As to the question of burden of search, the inventions are classified differently, necessitating different searches of the US Patents and literature. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-4, 6, 10-11, 15-38, 40-41, and 43-49 have been cancelled.

New Claim 50 has been added.

Claims 5, 7-9, 12-14, 39, 42, and 50 are currently pending and under consideration.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The specification on page 13, line 42 discloses the following embedded hyperlink, http:www.ebi.ac.uk/intepro. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of molecules that are complementary to a nucleotide sequence encoding a polypeptide comprising the amino acid SEQ ID NO: 16. However, the written description in this case only sets forth the nucleic acid sequence SEQ ID NO: 15 encoding a polypeptide comprising the amino acid SEQ ID NO: 16.

The specification teaches (page 7) that nucleic acids of the invention include, but are not limited to, molecules which encode a Serotonin receptor-like protein. With regard to these nucleic acids, the specification teaches that the nucleic acids can be those provided in SEQ ID NO: 15 or a fragment thereof, a mutant or variant nucleic acid whose bases may be changed corresponding to

the bases in SEQ ID NO: 15, or nucleic acids whose sequences are complementary to SEQ ID NO: 15. With regards to the complementary nucleic acids, the specification teaches that this includes nucleic acid fragments that are complementary to any of the nucleic acids of SEQ ID NO: 15. However, the written description only reasonably conveys one nucleic acid sequence consisting of SEQ ID NO: 15 that encodes the amino acid sequence SEQ ID NO: 16; and therefore, does not commensurate with the full scope of any nucleic acid that is complementary to a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 16. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of nucleic acid sequences that encompass the genus of molecules that are complementary to SEQ ID NO: 15 nor does it provide a description of structural features that are common to the nucleic acid sequence. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species consisting of SEQ ID NO: 15 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of molecules that are complementary to SEQ ID NO: 15, and therefore

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a nucleic acid that is complementary to SEQ ID NO: 15, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 50 is rejected under 35 U.S.C. 102(e) as being anticipated by Majumder *et al.* (WO 01/74851, April 6, 2000)

In the instant case, the claim is drawn to a nucleic acid molecule comprising a complement of a nucleic acid sequence encoding a polypeptide comprising the amino acid SEQ ID NO: 16.

Majumder *et al.* teaches (page 42, lines 15+, see attached) a NOV5a nucleic acid (SEQ ID NO: 9) which has 92.7% identity to the patentably disclosed nucleic acid of interest SEQ ID NO: 15. The patent further teaches that the NOV5a nucleic acid encodes a protein having 86.4 % identity to, and 97.6% similarity to the patently disclosed amino acid sequence SEQ ID NO: 16. Although the reference does not specifically teach a complementary nucleic acid, DNA itself is made up of two complementary strands of nucleotides as evidenced by Alberts *et al.* (Molecular Biology of

the Cell, see attached). Thus, it does not appear that the claimed language or limitations results in a manipulative difference in the nucleic acids when compared to the prior art disclosure.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 50 is further rejected under 35 U.S.C. 102(e) as being anticipated by Sutcliffe *et al.* (U.S. Patent 5,968,817, March 15, 1993).

Sutcliffe *et al.* teaches (Sequence Listing, see attached) a nucleic acid (SEQ ID NO: 1) which has 63.4% identity to the patentably disclosed nucleic acid of interest SEQ ID NO: 15. Although the reference does not specifically teach a complementary nucleic acid, DNA itself is made up of two complementary strands of nucleotides as evidenced by Alberts *et al.* (Molecular Biology of the Cell, see attached). Thus, it does not appear that the claimed language or limitations results in a manipulative difference in the nucleic acids when compared to the prior art disclosure.

Claims 5, 7-9, 12-14, 39, and 42 appear to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER